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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,820	01/05/2004	Douglas S. McNair	CRNC.103792	3634

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SHOOK, HARDY & BACON L.L.P.
Intellectual Property Department
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KANSAS CITY, MO 64108-2613

EXAMINER

NGUYEN, TRAN N

ART UNIT	PAPER NUMBER
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3626

MAIL DATE	DELIVERY MODE
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11/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/751,820	Applicant(s) MCNAIR, DOUGLAS S.	
	Examiner Tran Nguyen	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 07/24/2008.

Pending claim(s): 1. Amended claim(s): 1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim(s) 1 is/are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As per claim 1, this claim recites a “method” comprising a plurality of steps.

Examiner recognizes that the preamble recites “a computing environment”; however, the individual steps do not require any structure or apparatus to realize the recited functionality. To the contrary, the steps could be reasonably interpreted to encompass human beings performing the steps.

Therefore, the nominal recitation of structure in an otherwise ineligible method fails to make the method a statutory process. *Gottschalk v. Benson*, 409 U.S. 63 (1972) at 71-72.

The remainder of the claim fails to amount a statutory process for the following reasons.

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First, the steps do not require the particulars of another statutory class, i.e. machine, manufacture, composition of matter. Therefore, any structure capable of performing the recited functionality would be reasonably enveloped by the claim scope, including human beings.

Second, the claim does not produce a physical transformation. Examiner recognizes that the claim recites “presenting the representation... to a user using a display in the computing environment”; however, this limitation encompasses both hardware and software embodiments. Since the software *per se* embodiments enveloped by the claim are not statutory, at least some claim embodiments are directed towards mere *per se* data transformation without requiring any physical transformation to be performed by the software.

Therefore, the claim is directed towards nonstatutory subject matter.

To properly overcome this rejection, Applicant is suggested to amend the claim steps to require the particulars of another statutory class, and/or positively recite a physical transformation realized in hardware.

Applicant is also requested to point to the specification for support of the hardware implemented steps, and to provide a discussion of explicit, implicit, and inherent support available in the specification as originally filed.

Additional clarification is requested.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant-cited art number 11 of the IDS submitted 07/10/2007 (Weinert) in view of Ashton (Geographic Variations in Utilization Rates in Veterans Affairs Hospital and Clinics, copy provided to Applicant in the Office Action mailed 01/10/2007) and Chan (Access to physicians in underserved communities in Canada: something old, something new, copy provided to Applicant in the Office Action mailed 04/03/2008).

As per claim 1, Weinert discloses a method capable of:

(a) being computerized (page 458 column 2 paragraph 1);

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(b) providing a predictor variable or dependent variable in investigations of the relationship between rurality and health-care variables (page 463 column 2 paragraph 6) for a locality comprising a plurality of health care institutions (page 454 column 2 paragraph 3);

the method comprising:

(a) obtaining data pertaining to the distance to care and the population for county residences (It is noted that data on county residences are considered to be “a catchment area”) (page 455 column 2 paragraph 2);

(b) normalizing amounts and counts as measures of distance (It is noted that amounts and counts are considered to be “proband counts”) (page 456 column 2 paragraph 7);

(c) transforming the distance values using a Box-Cox power transformation (page 456 column 2 paragraph 8), wherein the distance value represents the distance to care (page 455 column 2 paragraph 2);

(d) transforming the population values using a Box-Cox power transformation (page 456 column 2 paragraph 9), wherein the population is measured in persons (page 459 Table 1);

(e) standardizing the distance and population values using standard deviation and signs, thereby transforming the distance and population values (page 457 column 1 paragraph 3);

(f) weighting the standardized transformed values (page 457 column 1 paragraph 4) and summing standardized values to form an initial index (It is

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noted that the initial index is considered to be “a provisional index”) (page 457 column 2 paragraph 1);

(g) standardizing the initial index to have a mean of zero and a standard deviation of one (page 457 column 2 paragraph 2);

(h) seeking the optimal choices for λ_1 and λ_2 such that the Anderson-Darling measure of deviation from normality minimized (page 458 column 1 paragraph 3-4);

(i) applying the optimal values of λ_1 and λ_2 to produce the rurality index (page 458 column 1 paragraph 1;

(j) analyzing the distribution to determine a grouping for the rurality index, and using tables of standard normal distribution to find percentiles and probabilities for the rurality index (page 458 column 2 paragraph 3);

(k) risk-adjusting access to care and health care utilization using the rurality index and distance categories (page 458 column 2 paragraph 2) to represent the differences in access to care due to distance (page 455 column 2 paragraph 3);

(l) displaying the results (It is inherent that a computer program computing optimal transformation values displays the results either as visual indicia to the user or as data parameters to another program) (page 458 column 2 paragraph 1).

Weinert does not disclose risk-adjusting using age.

Ashton discloses risk-adjusting based on age (page 34 column 1 paragraph 4).

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At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Ashton within the invention as disclosed by Weinert with the motivation of controlling for variations attributable to patient factors outside the control of the medical care system (Ashton; page 34 column 1 paragraph 4).

Weinert further teaches that the rurality index is capable of being used as a predictor variable or as a dependent variable in investigations of the relationships between rurality and health-care variables (page 463 column 2 paragraph 6).

Weinert does not teach “a display in the computing environment”.

Ashton teaches using VHA data bases to obtain computerized data (suggests “a display in the computing environment”) (page 32 column 1 paragraph 2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Ashton within the embodiment of Weinert with the motivation of automating calculations.

Weinert and Ashton do not teach “the clinical indicators assess quality of health services in the locale, the quality assessment including”:

- (a) “identifying under-resourced local health care needs”;
- (b) “monitoring prevention of medical complications”;
- (c) “comparing performance of the locale to other communities”.

Chan teaches a plurality of locale-specific measurements, comprising:

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(a) measuring areas that are “underserved” with respect to health care (page 329 paragraph 1), wherein a measure of rurality is used (page 332 Table 2);

(b) measuring the lack of primary care resulting in hospitalization (reads on “prevention of medical complications”) (page 335 paragraph 1);

(c) comparing a plurality of regions (page 336 paragraph 4).

All component parts are known. The only difference is the combination of “old elements” into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Chan within the embodiment of Weinert and Ashton, since the operation of the quality of care measurement is in no way dependent on the rurality indicator, and a standard quality of care measurement may be used with a rurality indicator to achieve the predictable result of measuring quality of care for rural areas (Chan; page 333 paragraph 2, Weinert; page 455 column 2 paragraph 3).

Response to Arguments

Applicant's arguments filed 07/24/2008 have been fully considered but they are not persuasive.

As per claim 1, on page 8 Applicant asserts the advantage of “easy-to-use and inexpensive screening tool”.

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In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a tool) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Assuming *arguendo* Applicant is referring to the "computing environment", which may be hardware or software (see the section above with respect to 35 USC 101), Examiner submits that Ashton teaches using computers to process data (page 32 column 1 paragraph 2). It is clear to one of ordinary skill in the art to leverage the power of technology to alleviate human-performed calculations.

On page 8 Applicant further asserts "the present invention is easy-to-use and inexpensive because it calculates risk-adjusted indicators using available data".

Ashton teaches using computers to interact with VHA data bases to obtain computerized data, thereby using existing data (page 32 column 1 paragraph 2).

On page 8 Applicant further asserts "the present invention can be used as a screening tool because it provides for recurring monitoring of locale-specific healthcare services".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., recurring monitoring) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

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specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In particular, it is not apparent how this un-recited feature is an apparent advantage of the claimed invention.

Assuming *arguendo* that this advantage is a latent property of the claim, Chan teaches that the entire purpose of measuring underserved communities is to send resources where they are most needed (page 347).

Therefore, the assert advantages do not distinguish the claimed invention over the applied art.

On page 8 Applicant argues that the applied art do not teach “screening, using recurring monitoring”.

This feature is addressed above, and incorporated herein.

On page 8 Applicant argues that the applied art do not teach “local-specific assessment” and “identify particular under-resourced needs in a particular locale”.

Chan specifically teaches measuring underservicing for particular region (page 334 paragraph 2 and throughout).

Therefore, the applied art suggest the claimed invention.

On page 8-9 Applicant argues that the applied art teach away from the claimed invention.

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Applicant's rationale for arguing that the applied art teaches away is that the applied art do not provide a flexible approach.

First, Applicant's teach-away argument is inadequate because Applicant does not discuss any portion of the applied art that criticize, discredit, or otherwise discourage the solution claimed. MPEP 2145 subsection XD.

If Applicant disagrees, Applicant is requested to provide a discussion of the applied art, including portions where the prior art discredit, criticize, or otherwise discourage the claimed invention.

Second, the asserted advantage has been addressed above, and incorporated herein.

In particular, Applicant asserts the advantage of using existing transactional records.

This feature is taught by Ashton in the discussion of accessing VHA data bases, as discussed above and incorporated herein.

Applicant also asserts the advantage of addressing inner cities.

Chan teaches both rural and urban settings (page 340 Table 4).

Therefore, the applied art suggest the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3626
10/28/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626